

## Message Text

UNCLASSIFIED

PAGE 01 STATE 070520  
ORIGIN HEW-06

INFO OCT-01 AF-08 EUR-12 EA-09 ISO-00 OES-06 SIG-02  
MED-03 COM-04 EB-08 /059 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:CCK  
APPROVED BY OES/APT/BMP: WJWALSH, III  
DHEW/PHS/OASH/OIH: RFISCHER  
EUR/EX:JLTULL(INFO)  
EA/ANP:HTNELSON(INFO)  
AF/S:FBCRUMP(INFO)

-----310713Z 080123 /23-11

P 302254Z MAR 77  
FM SECSTATE WASHDC  
TO AMEMBASSY CANBERRA PRIORITY  
AMEMBASSY BRUSSELS PRIORITY  
AMEMBASSY PARIS PRIORITY  
AMEMBASSY BONN PRIORITY  
AMEMBASSY OSLO PRIORITY  
AMEMBASSY PRETORIA PRIORITY  
AMEMBASSY LONDON PRIORITY  
AMCONSUL CAPE TOWN PRIORITY

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CAPE TOWN FOR EMB

E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO,AS,BE,FR,GW,NO,SF,UK R

SUBJECT: FDA ADVISORY - RECALL OF MEDICAL DEVICE -  
DISPOSABLE AUTOLOGOUS BLOOD TRANSFUSION SYSTEM - RECALL T-  
064-7

1. FDA ADVISES OF THE FOLLOWING MEDICAL DEVICE RECALL:

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SORENSEN RESEARCH COMPANY, BRAND OF STERILE DISPOSABLE COM-  
PONENTS OF THE RECEPTAL A.T.S. (AUTOLOGOUS TRANSFUSION  
SYSTEM) WHICH IS USED FOR SURGICAL AND EMERGENCY COLLECTION,  
FILTERING AND REINFUSION OF AUTOLOGOUS WHOLE BLOOD COMPO-  
NENTS ARE AS FOLLOWS:

COMPONENT	CATALOG NO.	HOW PACKAGED
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BLOODLINER-800CC            KGA-800L        5/BOX, 50  
LINER ASSEMBLY CONSISTING        CASE  
OF AN UPPER BAG AND A LOWER  
BAG WITH 170 MICRON FILTER

EMERGENCY BLOODLINER -        KGA-1900L        (UNKNOWN)  
1900 CC SINGLE, VINYL  
BLOOD BAG WITH 170  
MICRON PRE-FILTER

SUCTION TIP-WITH            ATS-S72        10/BOX  
AUTOMATIC PROPORTIONAL  
VALVE FOR MIXING ANTI-  
COAGULANT WITH BLOOD,  
HAVING A 72 INCH SUCTION  
TUBE FOR BLOOD COLLECTION  
AND A PARALLEL IV SET FOR  
ANTICOAGULANT SUPPLY

MICRO-AGGREGATE "SWANK"        ATS-F10        10/BOX  
FILTER WITH ATTACHED  
ADMINISTRATION SET

ANTICOAGULANT-500 CC        ATS-CPD500        12/BOX  
VENTED BOTTLE OF CITRATE  
PHOSPHATE DEXTROSE

ALL COMPONENTS ARE IDENTIFIED ON THE LABEL "SORENSEN RES-  
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EARCH COMPANY, P. O. BOX 15588, SALT LAKE CITY, UTAH  
84115". SORENSON IS THE MANUFACTURER OF ALL THE COMPON-  
ENTS EXCEPT THE ATS-CPD-500 WHICH SORENSON DISTRIBUTES  
AS AN OWN LABEL ITEM. THE KGA-1900-L COMPONENT WAS NOT  
ORIGINALLY PART OF THE SYSTEM, AND HAS BEEN MARKETED  
SINCE JUNE 1976. THIS COMPONENT CARRIES NO DIRECTIONS  
FOR USE.

ALL REPEAT ALL LOT NUMBERS OF THE (5) FIVE ITEMS ARE UNDER  
RECALL. COMPONENTS ARE DISTINGUISHABLE BY THE CATALOG  
NUMBERS.

MANUFACTURER/RECALLING FIRM:

THE MANUFACTURER AND/OR DISTRIBUTOR FOR ALL COMPONENTS IS  
THE SORENSON RESEARCH COMPANY. THE ONLY COMPONENT NOT  
MANUFACTURED BY SORENSON IS THE ATS-CPD 500, THE ANTI-  
COAGULANT WHICH IS MANUFACTURED UNDER SORENSON'S LABEL BY  
FENWAL LABORATORIES, DIVISION TRAVENOL LABORATORIES, INC.

MORTON GROVE, ILLINOIS 60053. HOWEVER, SORENSON IS THE RESPONSIBLE FIRM FOR ALL COMPONENTS.

2. REASON FOR RECALL:

FDA INSPECTION OF 2-10 FEBRUARY 1976 REVEALED SEVERAL COMPLAINTS OF INCORRECT PROPORTIONING OF THE CPD ANTICOAGULANT SOLUTION AS WELL AS INADEQUATE LABELING. ON 31 JANUARY 1977 SORENSON INDICATED THAT THEY INTENDED TO RECALL (VOLUNTARILY) ALL STERILE ITEMS WHICH WERE COMPONENTS OF THE SYSTEM SORENSON DELAYED RECALL DUE TO FEED BACK FROM MEDICAL PROFESSIONALS WHO CLAIMED RECALL WOULD PREVENT LIFESAVING USE OF COMPONENTS. SORENSON ISSUED RECALL LETTERS ON 11 FEBRUARY 1977. ATS SYSTEM BEING REDESIGNED BUT SYSTEM NOT YET READY FOR MARKETING.

3. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO UNCLASSIFIED

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DETERMINE IF THEY HAVE RECEIVED RECALL NOTIFICATION(LETTER) BY SORENSON DATED 31 JANUARY 1977. LETTER REQUESTS RETURN OF ALL REPEAT ALL ATS ITEMS NOW IN POSSESSION FOR FULL CREDIT TO FIRM BY CHEAPEST WAY, COLLECT.

4. CONSIGNEES AS FOLLOWS:

TELECTRONICS PTY-LTD      MESSRS. HOSP.PRODUCTS PTY  
2 SIRIUS ROAD N.S.W.      LTD  
2066 AUSTRALIA      P O BOX 758  
CAPETOWN, SO. AFRICA

DECKERS

O. L. VROUSTRAT 29      SIMONSON & WEEL LTD  
B-3000 LEUVEN-BELGIUM      HATHERLEY HOUSE  
HATHERLEY ROAD

COOPERATION EUROPEENE DE      SIDCUP KENT DA14 BR  
FOURNITURES HOSPITALIER      ENGLAND  
24 RUE AMELOT  
PARIS 11 FRANCE

LUTZ & COMPANY  
ALLEGEMEINE TRANSPORT GESELLSCH  
VORM., GONDRAND & MANGILL MGB  
AIRPORT OFFICE COLOGNE  
GERMANY

PLESNER FARMASOYTISK  
ASTVETENVEIEN 22  
POSTBOKS 6028 ETT  
OSLO 6 NORWAY  
CHRISTOPHER

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NNN

## Message Attributes

**Automatic Decaptioning:** X  
**Capture Date:** 01-Jan-1994 12:00:00 am  
**Channel Indicators:** n/a  
**Current Classification:** UNCLASSIFIED  
**Concepts:** MEDICAL EQUIPMENT, RECALLS  
**Control Number:** n/a  
**Copy:** SINGLE  
**Sent Date:** 30-Mar-1977 12:00:00 am  
**Decaption Date:** 01-Jan-1960 12:00:00 am  
**Decaption Note:**  
**Disposition Action:** n/a  
**Disposition Approved on Date:**  
**Disposition Case Number:** n/a  
**Disposition Comment:**  
**Disposition Date:** 01-Jan-1960 12:00:00 am  
**Disposition Event:**  
**Disposition History:** n/a  
**Disposition Reason:**  
**Disposition Remarks:**  
**Document Number:** 1977STATE070520  
**Document Source:** CORE  
**Document Unique ID:** 00  
**Drafter:** JRWEINROTH, M.D.:CCK  
**Enclosure:** n/a  
**Executive Order:** N/A  
**Errors:** N/A  
**Expiration:**  
**Film Number:** D770110-0232  
**Format:** TEL  
**From:** STATE  
**Handling Restrictions:** n/a  
**Image Path:**  
**ISecure:** 1  
**Legacy Key:** link1977/newtext/t1977035/aaaaaelr.tel  
**Line Count:** 170  
**Litigation Code IDs:**  
**Litigation Codes:**  
**Litigation History:**  
**Locator:** TEXT ON-LINE, ON MICROFILM  
**Message ID:** cf1f7db6-c288-dd11-92da-001cc4696bcc  
**Office:** ORIGIN HEW  
**Original Classification:** UNCLASSIFIED  
**Original Handling Restrictions:** n/a  
**Original Previous Classification:** n/a  
**Original Previous Handling Restrictions:** n/a  
**Page Count:** 4  
**Previous Channel Indicators:** n/a  
**Previous Classification:** n/a  
**Previous Handling Restrictions:** n/a  
**Reference:** n/a  
**Retention:** 0  
**Review Action:** RELEASED, APPROVED  
**Review Content Flags:**  
**Review Date:** 20-Sep-2004 12:00:00 am  
**Review Event:**  
**Review Exemptions:** n/a  
**Review Media Identifier:**  
**Review Release Date:** n/a  
**Review Release Event:** n/a  
**Review Transfer Date:**  
**Review Withdrawn Fields:** n/a  
**SAS ID:** 3080282  
**Secure:** OPEN  
**Status:** NATIVE  
**Subject:** FDA ADVISORY - RECALL OF MEDICAL DEVICE - DISPOSABLE AUTOLOGOUS BLOOD TRANSFUSION SYSTEM - RECALL T- 064-7  
**TAGS:** OGEN, ETRD, EIND, TBIO, AS, BE, FR, GE, NO, SF, UK  
**To:** CANBERRA BRUSSELS MULTIPLE  
**Type:** TE  
**vdkgvwkey:** odbc://SAS/SAS.dbo.SAS\_Docs/cf1f7db6-c288-dd11-92da-001cc4696bcc  
**Review Markings:**  
Margaret P. Grafeld  
Declassified/Released  
US Department of State  
EO Systematic Review  
22 May 2009  
**Markings:** Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 22 May 2009